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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBIC-043/A	1842

7590 06/30/2004

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EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/399,083	CALDERWOOD ET AL.	
	Examiner	Art Unit	
	Deepak R Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11 and 46-52 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 11 and 48-51 ~~is/are~~ are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 46, 47 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 26, 2004 has been entered.

Claims 1-8, 10-11 and 46-52 are pending in this application.

Election/Restrictions

Applicant is reminded that the examination is based on the elected species (as indicated in previous office actions) which reads on claims 1-8, 10, 46, 47 and 52. Claims 11 and 48-51 are withdrawn from further consideration as being drawn to nonelected species (see MPEP §803.02) pursuant to 37 CFR 1.142(b).

Claims 1-8, 10, 46, 47 and 52 are considered to the extent readable on the examined subgenus, i.e., structural formula of claim 1 wherein ring A is phenyl; L is -NH-SO₂-; j is 0; R₃ is substituted phenyl; R₂ is H; and R₁ is cyclopentyl. All other definitions of the variables from claims 1-8, 10 and 47 and species other than that of the above subgenus from claim 46 are withdrawn from consideration as being drawn to nonelected species.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- In claim 1, in the definition of R_c , the term $-W-(CH_2)_t-NR_dR_e$ is confusing. There is a mismatch in the parenthesis. Further, this term is not supported by the specification. The correct term appears to be -- $-W-(CH_2)_t-NR_dR_e$ --as disclosed in the specification at page 21, line 10.
- In claim 1, in the definition of R_c , the recitation “ $-W-(CH_2)_t-NR_dR_e$, $-W-(CH_2)_t-O$ -alkyl, $-W-(CH_2)_t-S$ -alkyl, $-W-(CH_2)_t-OH$ or” is repeated (see page 3, lines 7-8).
- In claim 1, in the definition of L , the terms “ $-N(R)S(O)N(R)-$; $-N(R)S(O)_2N(R)-$ ” are repeated, see page 3, line 29 and page 4, line 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/41525. The instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., page 14, lines 9-14, 22-23, etc.

Applicant's arguments filed on March 26, 2004 are fully considered but they were not deemed to be persuasive. Applicant argues that the instant claims do not include compounds wherein Ring A is substituted by methoxy or hydroxy. However, the substituent list of Ring A includes a moiety R_c which is defined to be $-W-(CH_2)_t-O-alkyl$ or $-W-(CH_2)_t-OH$ wherein W is defined to be a bond, etc. and t is an integer 0-6. The above groups represent alkoxy or hydroxy respectively wherein W is a bond and t is 0 and therefore, the substituents on ring A of the instant claims includes methoxy and hydroxy.

2. Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,001,839 (filed March 17, 1998). The instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., col. 10, lines 5-15, 26-27, 30-31, etc. The instantly amended claim 1 includes compounds wherein ring A can be substituted by R_c which is defined to be $-W-(CH_2)_t-O-alkyl$ or $-W-(CH_2)_t-OH$. The above groups represent alkoxy or hydroxy respectively wherein W is a bond and t is 0 and therefore, the substituents on ring A of the instant claims includes methoxy and hydroxy.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

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CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that the instant application is a CIP of S.No. 09/042,702, which issued as the reference patent U.S. 6,001,839 and will have the same expiration date. This is not sufficient to overcome the above rejection. Applicant's attention is directed to MPEP § 706.02(b) [R-1] which provides how a rejection under 35 U.S.C. 102(e) may be overcome.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

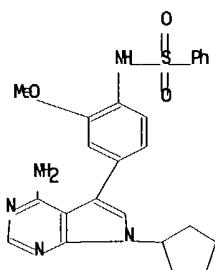
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Claims 1-8, 10, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I in page 2 wherein R_3 is represented by formula (a) wherein the phenyl ring of formula (a) is optionally further substituted (see page 3, lines 6-9); A is NHSO_2 (page 3, line 10) and R_5 is optionally substituted phenyl. The reference further discloses several species that fall within the above genus, see pages 10-14, particularly page 14, lines 9-14 and 22-23. The compounds are taught to be useful as pharmaceutical therapeutic agents having protein kinase inhibition activity, see the entire document. Claims 1-8, 10 and 47 read on reference disclosed compounds, see the rejection under 35 U.S.C. 102(a) above. Claim 46 differs from the reference by reciting specific species of the reference genus. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

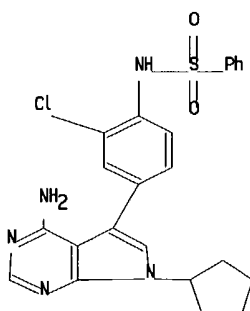
Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that the reference does not provide any suggestion or motivation to modify the reference compounds to arrive at claimed compounds. This is not found to be

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persuasive because the reference clearly teaches 4-amino-7H-pyrrolo[2,3-d]pyrimidin-5-yl compounds having an optionally substituted phenyl ring (wherein the optional substituents include alkoxy, halo, etc. see the list in page 3, lines 26-28) attached at the 5-position, which phenyl is further substituted with -A-R₅. The reference also discloses a species falling within the above genus, see e.g., the compound of Example 34 which is depicted below for convenience:



Claim 46 of the instant application includes the species N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-chlorophenyl)-1-benzenesulfonamide (lines 12-13) which is depicted below for convenience:



As can be seen from the above two structural formula, the only difference between the reference compound and the instantly claimed compound is the optional substituent at the 2-position. The reference discloses a methoxy substituent and further teaches the equivalency of alkoxy, halogen, etc. as all these are taught to be alternatives as substituents on the phenyl ring. Therefore, the reference clearly suggests the instantly claimed compounds. Further, both the

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reference compounds as well as the instantly claimed compounds are disclosed to be useful as tyrosine kinase inhibitors.

Applicant cites *In re Grabiak* and argues that 'there must be adequate support in the prior art in order for to complete a *prima facie* case'. First, applicant's attention is directed to the situation in *Grabiak*, which was different from the instant application because the references in that case did not provide evidence to substitute sulfur for oxygen, and therefore, the court concluded that 'there must be adequate support in the prior art for the ester/thioester change in structure, in order to complete the *prima facie* case'. The instant scenario is different because the reference clearly teaches the equivalency between the various substituents in that any of the substituent from the list provided can be selected to be substituted on the phenyl group and further the reference provides examples of such substituted phenyl groups and thus, provides sufficient motivation to one of ordinary skill in the art to use any of the substituents on the phenyl group. Therefore, for all the reasons of record, in the absence of unexpected properties, it is maintained that the instantly claimed compounds are obvious over the prior art disclosure.

Duplicate Claims

Applicant is advised that should claim 6 be found allowable, claim 7 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 7 does not further limit the scope of claim 6.

Allowable Subject Matter

Claim 52 is allowed. The closest references of record, US'839 or WO'525 do not teach or fairly suggest the instantly claimed species, wherein the second phenyl ring is substituted with a 2-OCF₃. The reference does not teach that the phenyl ring of R₅ be substituted with a haloalkoxy group.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

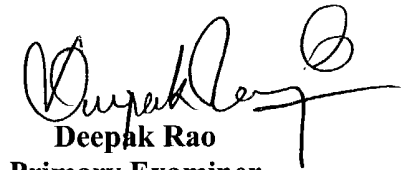
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deepak Rao
Primary Examiner
Art Unit 1624

June 24, 2004